DOI: 10.1136/annrheumdis-2019-eular.5469

THU0157

REASONS FOR NON-PARTICIPATION IN A RANDOMIZED CONTROLLED TRIAL COMPARING TWO SEASONAL INFLUENZA VACCINES IN RHEUMATOID ARTHRITIS PATIENTS

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Background: Low recruitment rates (12%) into influenza vaccine studies are reported among healthy older adults. Fear of side effects, lack of insight into personal risk status, and doubts about vaccine efficacy are the most commonly reported reasons for non-participation¹. Rheumatoid arthritis (RA) patients are also at high risk for influenza and benefit from yearly immunization². A number of influenza vaccines are currently available; however, it is unknown which vaccine(s) provides optimal protection to RA patients. Estimating participation rates is key for designing studies to address that issue.

Objectives: To define the rate of non-participation and reported reasons for refusing entry into a randomized clinical trial (RCT) comparing two influenza vaccine formulations (NCT02936180 - ClinicalTrials.gov).

Methods: Seropositive RA patients from McGill University Health Centre, on stable treatment prior to recruitment (≥ 3 months), were invited by their treating rheumatologists to participate in the study. A vaccine nurse contacted participants from Year 1 (Y1) and those from Year 2 (Y2) encountered a recruiter immediately after their rheumatologist's appointment. Patients who agreed to participate signed the consent form and were later contacted by a vaccine nurse to schedule their appointment. Reasons for non-participation were documented.

Results: Over two influenza seasons, 692 RA patients were invited to participate in the study. The non-participation rate was 59.5% (Y1=64.6%, Y2= 53.1%, $p=0.1$). Non-participants and participants did not differ in age or sex (age mean $\pm$ SD: 61.7 $\pm$ 14.7 vs 60.9 $\pm$ 12.9, $p=0.5$; female sex%: 76.8 vs 79.9, $p=0.33$). Inclusion and exclusion criteria resulted in the loss of 17 (4.1%) and 19 (4.6%) subjects, respectively. The three most commonly reported reasons for non-participation were vaccine misconceptions ($n=49$, 20.4%), reluctance to participate in a clinical trial ($n=35$, 14.6%), and lack of available time ($n=29$, 12.1%). Thirty-one patients reported more than one reason for non-participation. Reasons for non-participation were similar according to sex and patient age ($>$ or $<$ 65 years).

Conclusion: Only half of eligible RA patients accepted to be enrolled in this influenza vaccine study. Enhancing patient literacy on vaccines and the relevance of conducting clinical trials is essential to optimize both recruitment to such trials and immunization rates.

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Acknowledgement: The Arthritis Society - Canada

Disclosure of Interests: Mariana Useche: None declared, Jonathan Starr: None declared, Katherine Rodriguez: None declared, Agnihotram Ramanakumar: None declared, Marie Hudson Grant/research support from: Unrestricted research funds from Bristol-Myers Squibb, Brian Ward: None declared, Ines Colmegna: None declared

DOI: 10.1136/annrheumdis-2019-eular.6381

THU0158

IMPAIRED OLFACTORY FUNCTION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Recent studies indicated that rheumatic disorder can be associated with olfactory loss.

Objectives: To specifically investigate chemosensory function in patients with rheumatoid arthritis (RA) by valid and reliable psychophysical tests and compare them to healthy controls.

Methods: We investigated 212 RA patients (43 men, 169 women; mean age 59 years) and compared their results to 30 healthy controls (10 men, 20 women; mean age 40 years). All participants received standardized olfactory (odor thresholds, odor discrimination and identification for suprathreshold testing) and gustatory tests (taste sprays – suprathreshold taste function; taste strips – quasi-threshold gustatory test). In addition, blood chemistry was also assessed (e.g., for CRP, RA factors, and anti-CCP).

Results: RA patients rated their senses of smell and taste to be as good as that of controls. However, in RA patients 4% were found to be anosmic, and 36% to be hyposmic. These numbers were 0 and 20%, respectively, in controls. RA patients exhibited significantly lower scores in odor identification and discrimination. Gustatory test scores were also decreased in RA patients. No such differences were found for odor thresholds. Interestingly, the changes in olfactory and gustatory function neither correlated with disease duration nor with indicators of RA activity or severity like C-reactive protein, rheumatoid factors, anti-CCP antibodies or DAS28-Score. Moreover, there was no correlation between olfactory dysfunction and treatment with DMARDs, e.g. amount of MTX, or Tumor necrosis factor α inhibitors.

Conclusion: These results indicate that olfactory and gustatory function is significantly decreased in patients with RA. This decrease in function seems to be unnoticed by most patients which may be due to the fact that RA patients have no complete loss of function (anosmia), but still function in the range of hyposmia or even normosmia. Importantly, the changes in olfactory function are not observed at the level of odor thresholds but only for suprathreshold tasks, which may suggest that the decrease in function is due to higher-order central-nervous processing of olfactory information. In addition, the lack of correlations between disease parameters and chemosensory dysfunction indicates that the decrease in chemosensory function may be a trait characteristic of RA patients.

Disclosure of Interests: Joerg Wendler Consultant for: Chugai, Roche, AbbVie, Novartis, Janssen-Cilag, Speakers bureau: Chugai, Roche, AbbVie, Novartis, Janssen-Cilag, Khang Tran: None declared, Martin Aringer Grant/research support from: Roche, Consultant for: AstraZeneca and Eli Lilly, Florian Schuch Consultant for: Celgene, Lilly, UCB, Roche, Sanofi-Aventis, Abbvie, Novartis, Speakers bureau: Celgene, Lilly, UCB, Roche, Sanofi-Aventis, Abbvie, Stefan Kleinert Grant/research support from: Novartis, Consultant for: Novartis, UCB, Chugai, Celgene, Medac, Roche, Abbvie, Speakers bureau: Novartis, UCB, Chugai, Celgene, Medac, Roche, Abbvie, Antje Haehner: None declared, Thomas Hummel: None declared

DOI: 10.1136/annrheumdis-2019-eular.6134

THU0159

RISK FACTORS FOR DEVELOPING SARCOPENIA IN PATIENTS WITH RHEUMATOID ARTHRITIS AT 2 YEARS: FROM THE CHIKARA STUDY

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Background: Patients with rheumatoid arthritis (RA) are at higher risk of sarcopenia due to joint dysfunction and chronic inflammation. The prospective observational CHIKARA study (Correlation research of sarcopenia, skeletal muscle and disease activity in rheumatoid arthritis; registration number UMIN000023744) was started in 2016 to clarify the correlation between RA disease activity and sarcopenia. We reported that glucocorticoid use and low body fat were independent risk factors for developing sarcopenia at 1 year in RA patients last year.

Objectives: Risk factors for sarcopenia were investigated over a 2-year period this time.

Methods: 100 patients (78 female, average age 68 years) enrolled in the prospective CHIKARA study underwent examinations of body composition (body weight, muscle mass, fat mass, predicted bone mass, etc.; measured by a body composition analyzer (MC-780A; TANITA, Tokyo, Japan)), laboratory data, disease activity, Health Assessment Questionnaire (HAQ), and treatment condition at baseline and at 2 years. Sarcopenia was diagnosed using the criteria of the Asia Working Group on Sarcopenia. Of 64 patients without sarcopenia at baseline, those who developed sarcopenia at 2 years were identified, and risk factors were investigated by univariate and multivariate analyses.

Results: Six patients (9.4%) developed sarcopenia during the 2-year follow-up. Glucocorticoid use >5 mg/day was significantly higher ($p=0.009$), and MMP3 ($p=0.018$) and HAQ ($p=0.045$) were significantly increased in the patients who developed sarcopenia during the 2-year follow-up. Sarcopenia development was significantly associated with male sex ($r=0.28$, $p=0.03$), age ($r=0.27$, $p=0.03$), glucocorticoid use >5 mg/day ($r=0.33$,

$p < 0.01$), CRP ($r = 0.33$, $p < 0.01$) at baseline, Δ MMP3 ($r = 0.30$, $p = 0.02$), and Δ HAQ ($r = 0.25$, $p = 0.04$) on univariate analysis. Multivariate analysis identified no independent factors (Table 1)

Table 1. Risk factors for developing sarcopenia in patients with rheumatoid arthritis

	Univariate		Multivariate		
	R value	p value	Odds ratio	95% CI	P value
Male sex	0.28	0.02	-	-	-
Age	0.27	0.03	1.05	0.92-1.20	0.47
GC use >5mg/day	0.33	<0.01	10.20	0.45-229.0	0.14
Δ MMP3	0.30	0.02	1.02	0.99-1.04	0.08
Δ HAQ	0.25	0.04	1.26	0.94-1.67	0.11

GC: glucocorticoids, CI: confidence interval, Δ : change from baseline to 2 year

Conclusion: Male sex, old age, glucocorticoid use >5 mg/day, and high elevations of MMP3 and HAQ are associated with developing sarcopenia at 2 years in RA patients.

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Acknowledgement: Yutaro Yamada

Disclosure of Interests: Yutaro Yamada Speakers bureau: Abbvie, Chugai, Mitsubishi Tanabe, Masahiro Tada Speakers bureau: Abbvie, Astellas Pharma, Bristol-Myers Squibb, Chugai Pharmaceutical, Eisai, Janssen Pharmaceutical, Mitsubishi Tanabe Pharma Corporation, Ono Pharmaceutical, Pfizer Japan, Takeda Pharmaceutical

, Koji Mandai: None declared, Noriaki Hidaka: None declared, Kentaro Inui Speakers bureau: Takeda Pharmaceutical, Pfizer Japan, Daiichi-Sankyo Co.Ltd., Abbvie, Mitsubishi Tanabe Pharma Corporation, Janssen Pharmaceutical, Chugai Pharmaceutical, Ono Pharmaceutical, Eisai Co. Ltd., Eli-Lilly, Nippon Kayaku Co.,Ltd., Maruho Co.,Ltd, Kaken Pharmaceutical Co.,Ltd., Hiroaki Nakamura: None declared

DOI: 10.1136/annrheumdis-2019-eular.1399

THU0160

FEATURES OF LIPID PROFILE INDICATORS IN PATIENTS WITH RHEUMATOID ARTHRITIS IN CONNECTION WITH ARTERIAL HYPERTENSION

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Background: Patients with rheumatoid arthritis (RA) have an early development of endothelial dysfunction, an increase of the atherogenicity index (AI), and a high risk of fatal cardiovascular events. The presence of arterial hypertension (AH) in patients with RA accelerates the process of early atherogenesis and increases the risk of fatal cardiovascular events.

Objectives: To evaluate the dynamics of lipid profile changes in patients with RA in combination with AH.

Methods: It was examined 47 patients with RA in combination with AH (by all patients was discovered I stage/2 degree of AH). The age of the patients ranged from 18 to 72 years. Among the surveyed group dominated men (41 patients). All patients were assessed for the levels of total cholesterol (TC), low density lipoprotein (LDL), very low density lipoprotein (VLDL), triglycerides (TG), high density lipoprotein (HDL), AI (AI = TC - HDL/LDL), antibodies to modified citrulline vimentin (anti-MCV), rheumatoid factor (RF), C-reactive protein (CRP) before treatment. All patients were also assessed for the risk of death for 10 years by the SCORE scale (> 15% - very high risk, 10-14% high, 5-3% - moderate, <1% - low) and RA activity by DAS28 score.

Results: Due to the obtained data, it can be asserted, that in patients with seronegative RA the moderate risk by SCORE was prevalent, and among seropositive RA patients– high risk. The high level of anti-MCV titres was directly correlated with the risk of the death by SCORE ($p > 0.05$, $r = 0.64$). We found that patients with RA and AH had relatively low levels of TC (5.82 ± 2.21 mmol/L) and LDL (2.82 ± 0.81 mmol/L), but the AI in these patients was 4.42 ± 0.68 . It was measured the correlation between the levels of LDL and the activity of the inflammatory

process DAS28, the level of CRP and the duration of RA ($r = 0.56$, $p < 0.05$, $r = 0.49$, $p < 0.05$, $r = 0.53$; $p < 0.05$, respectively). There was also a reverse correlation between the duration of RA and the level of HDL ($r = -0.47$; $p < 0.05$).

Conclusion: 1. Seropositivity, high activity and anamnesis of RA for more than 10 years are the factors, that are associated with high risk of fatal cardiovascular events. 2. In patients with RA in combination with AH, serum lipid levels have paradoxical ratio, resulting in lower levels of TC and LDL associated with an increased risk of cardiovascular events ("lipid paradox"). 3. The presence of high anti-MCV titres serves as a prognostically unfavorable feature of the course of RA and AH, since its association with a high risk of fatal cardiovascular events.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.901

Rheumatoid arthritis - non biologic treatment

THU0161

ORAL VERSUS SUBCUTANEOUS METHOTREXATE IN RECENTLY DIAGNOSED RHEUMATOID ARTHRITIS: DO WE GET THE SAME RESULTS?

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Background: As we know, the use of disease modifying antirheumatic drugs (DMARDs) improves the overall prognosis of rheumatoid arthritis (RA) specially when treatment is started early in the course of the disease.

The most widely used DMARD is methotrexate (MTX) mainly because of its favorable efficacy-toxicity ratio. However, there is a lot of variability using MTX when it comes to dosage and route of administration; and little research on the overall response of patients to the different strategies used.

Objectives: To compare the clinical response of oral (PO) versus subcutaneous (SC) MTX in recently diagnosed RA patients with no previous use of DMARDs. We evaluated the data collected at baseline, the 3rd, 6th and 12th month after the beginning of MTX treatment.

Methods: This descriptive, observational, longitudinal retrospective study was achieved using a cohort of patients with recently diagnosed RA in which treatment with MTX was started between August 1st 2015 to September 1st 2018. We collected demographic and clinical data, disease activity markers, MTX and corticoid dosage, routes of administration and treatment changes.

Results: In total, 52 patients were included of which 39 (75%) were women, with an average age of 57.56 years. There was a mean of 26 weeks between the first symptoms and the beginning of MTX.

Abstract THU0161 – Table 1.

	Total	Oral	Subcutaneous	(p)
Patients n(%)	52(100)	25(48.1)	27(51.9)	
Mean Starting MTX dose (SD)	12.6(+/-2.5)	11.1(+/-2)	13.98(+/-2.2)	<0.0001
Mean Starting Prednisone dose (SD)	6.21(+/-6.2)	5.92(+/-4.3)	6.48(+/-7.5)	0.74
Mean Starting Painful Joint Count (SD)	9.5(+/-6.9)	8.56(+/-5.9)	10.41(+/-7.5)	0.34
Mean Starting Swollen Joint Count(SD)	5.38(+/-6.6)	5.04(+/-4.6)	7.34(+/-7.8)	0.2
Mean Starting CRP (SD)	1.67(+/-2.2)	1.51(+/-2.4)	1.76(+/-1.8)	0.69
Mean Starting ESR (SD)	27.3(+/-19.6)	30.44(+/-20)	24.22(+/-18.4)	0.25

Abstract THU0161 – Figure 1